IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Michael W. Johnson**
Application No.:	**09/880615**
Filed:	**June 13, 2001**
For:	**Stent Drug Delivery System**
Examiner:	**Jermie E. Cozart**
Group Art Unit:	**3726**

Mail Stop <u>Appeal Brief-Patents</u>
Commissioner for Patents
P.O. Box 1450   **Docket No.: S63.2N-6531-US03**
Alexandria, VA 22313-1450

REPLY BRIEF ON APPEAL

This is a Reply Brief on Appeal is submitted in response to the Examiner's

Answer for the above-identified application. This reply brief is submitted in accordance with 37

C.F.R. § 41.41.

Remarks

Applicant first wishes to clarify some remarks that were made in the

Supplemental Appeal Brief filed October 24, 2005. In the Brief, Applicant stated:

> In multiple responses to both these assertions, Applicant has pointed out that this
> is not consistent with column 4 lines 58-64 of Yan which teaches uniform porosity and the
> undesirability of areas of different porosity. As the explicit language of the Yan reference
> teaches the undesirability of areas of different porosity, it does not make sense that Yan would
> teach longitudinally spaced regions of different predetermined physical porosities. In fact, Yan
> teaches away from such a teaching; one would never predetermine to produce the very thing that
> is undesirable (i.e. non-uniform porosity)

Applicant wishes to clarify that the above discussion relates to the teaching in Yan (US 5843172)
concerning the desirability of consistent pore size *along the length* of the stent.

Applicant maintains that the combination of Yan and Solovay is not a proper combination and, even if it were made, would not disclose all of the elements of the instant claims.

First, Yan stresses the importance of consistent pore size to ensure that drugs are evenly distributed throughout the stent as well as of a consistent distribution to ensure that the tissue in contact with the stent will receive an even distribution of a therapeutic agent (see col. 4, lines 54-62, reproduced below):

> Pore size is a function of particle size and dimension. In one embodiment of the present invention illustrated in FIG. 3, the particles 24 are generally spherical. Size of the pore 18, particularly with generally spherical particles, is proportional to particle size. When the particles 24 have inconsistent size, smaller particles tend to fill the gaps between the larger particles. Thus, the porosity of such particles are less predictable. Consistent pore size is also important to ensure that drugs are evenly distributed throughout the stent. Consistent distribution on the other hand ensures that the tissue in contact with the stent will receive an even distribution of a therapeutic agent.

The tissue will not receive an even distribution of a therapeutic agent if different regions along the *length* of the stent have different porosities. Therefore, one of ordinary skill in the art would not modify Yan to have regions of different porosities along the length of the stent.

Even if one were, for the sake of argument, to combine the references, Applicant maintains that the result would be the manufacture of a Yan stent with a Solovay cover, and not, the manufacture of a coverless Yan device. The manufacture of a Yan stent with a Solovay cover does not meet the instant claim limitations because the claims require cutting a stent from a tube having at least two different longitudinally spaced regions of different predetermined porosities. Moreover, one of ordinary skill in the art would not be expected to resort to the more

difficult manufacturing techniques which would be expected to be required in the manufacture of a Yan stent which has been modified to have different regions of different porosity.

Conclusion

The Examiner has not shown motivation to combine the references and even when combined the teachings of these patents still fail to teach or suggest the method of any of the claims 23, 24, 26-30, 32, 33, and 35-40.   Claims 23, 24, 26-30, 32, 33, and 35-40 therefore are not obvious from Yan in view of Solovay or from Yan in view of Solovay and Richter. The Board is respectfully requested to reverse the rejections with instruction to pass the application to issue.

Respectfully submitted,

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Date: December 18, 2006

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